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K051425, 12

510(k) Summary

Trade Name:	Nexus Helix Super Soft CSR
Generic Name:	Neurovascular Embolization Device
Classification:	Class II, 21 CFR 882.5950
Submitted By:	Micro Therapeutics, Inc. 2 Goodyear Irvine, California 92618
Contact:	Florin Truuvert

Predicate Device:

Number	Description	Predicate For	Clearance Date
K050543	Nexus Detachable Coil System	Nexus Detachable Coil, Helix Super Soft CSR	April 27, 2005

Device Description

The Nexus Helix Super Soft CSR are platinum alloy coils, enlaced with absorbable polymer fibers, and attached to a stainless steel guiding system with a radiopaque positioning coil. Nexus Helix Super Soft CSR coils are designed for use with the NXT Detachment System specifically designed for coil detachment. The NXT Detachment System is sold separately.

Indication For Use

The Nexus Detachable Coils are intended for the endovascular embolization of intracranial aneurysms that – because of their morphology, their location, or the patient's general medical condition – are considered by the treating neurosurgical team to be a) very high risk for management by traditional operative techniques, or b) be inoperable. The Nexus Detachable Coils are also intended for the embolization of other neuro vascular abnormalities, such as, arteriovenous malformations and arteriovenous fistulae.

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Verification and Test Summary Table

Bench Testing	Result
Coil Deformation	Met established criteria
Dimensional & Visual Analysis	Met established criteria
Coating Integrity	Met established criteria
Force Transfer	Met established criteria
Ease of Delivery/Coil Frictional Characteristics	Met established criteria
Fiber endurance Testing	Met established criteria
Reliability After Fatigue & Premature Detachment	Met established criteria
Fiber Pull-Out	Met established criteria
Tensile Strength	Met established criteria
Particulate Generation – Adjusted Particles / 1 mL	Met established criteria
PGLA Tensile Testing	Met established criteria
Packaging Integrity	Met established criteria

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the Nexus Helix Super Soft CSR coils compared with the predicate device Nexus Detachable Coils.

The two devices have the same intended use,

- Use the same operating principle,
- Incorporate the same basic design,
- Use similar construction and material,
- Are packaged and sterilized using same processes.

In summary, the Nexus Helix Super Soft CSR coils described in this submission are, in our opinion, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 22 2005

Ms. Florin Truuvert
Regulatory Affairs Manager
Micro Therapeutics Incorporated
2 Goodyear
Irvine, California 92618

Re: K051425
Trade/Device Name: Nexus Detachable Coil, Helix Super Soft CSR
Regulation Number: 21 CFR 882.5950
Regulation Name: Artificial embolization device
Regulatory Class: II
Product Code: HCG
Dated: May 31, 2005
Received: June 1, 2005

Dear Ms. Truuvert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051425

Indications for Use

510(k) Number (if known):

Device Name: Nexus Detachable Coil, Helix Super Soft CSR

Indications For Use:

The Nexus Detachable Coils are intended for the endovascular embolization of intracranial aneurysms that – because of their morphology, their location, or the patient's general medical condition – are considered by the treating neurosurgical team to be a) very high risk for management by traditional operative techniques, or b) be inoperable. The Nexus Detachable Coils are also intended for the embolization of other neuro vascular abnormalities, such as, arteriovenous malformations and arteriovenous fistulae.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices
510(k) Number K051425

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